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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,816	08/27/2001	Elliott Farber	14358-314	2827

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EXAMINER
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SHARAREH, SHAHNAM J.

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 06/04/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Offic Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/939,816	FARBER, ELLIOTT
	<b>Examiner</b>	<b>Art Unit</b>
	Shahnam Sharareh	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 8/27/01, 2/12/03.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-11,20,21,24,28,30,32,34-36,38,39,42-44,48-56,59-63,66-70 and 73-76 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) Interview Summary (PTO-413) Paper No(s). 9.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

Continuation of Disposition of Claims: Claims withdrawn from consideration are Claims 12-19, 22-23, 25, 27, 29, 31, 33, 36-37, 40-41, 45-47, 57-58, 64-65, 71-72.

## DETAILED ACTION

Claims 1-76 are pending.

### ***Election/Restrictions***

1. Applicant's election of species of Applicators having beeswax and an anionic emulsifier as the emulsifier system in Paper No. 8 is acknowledged. Claims 1-11, 20-21, 24,26, 28, 30, 32, 34, 35, 38-39, 42-44, 48-56, 59-63, 66-70, 73-76 are directed towards the elected species and is under consideration. Claims 12-19, 22-23, 25, 27, 29, 31, 33, 36-37, 40-41, 45-47, 57-58, 64-65, 71-72 are withdrawn from further consideration because they are not directed towards the elected species.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-11, 20-21, 24, 26, 28, 30, 34-35, 38-39, 42-44, 48-56, 59-63, 66-70, 73-76 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 14, 18, 20, 22, 24, 26, 28-29, 32-33,

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36-38, 42-46 of U.S. Patent No. 6,281,236 (US '236) in view of Venkitaraman et al US Patent 5,871,762 or Yamanaka et al US Patent 5,176,916.

The patented claims of US '236 are directed to topical oil-in-water emulsions comprising allantoin, beeswax, an anionic emulsifier, and at least one herbal extract, chelating agent, inorganic acid, emollients or a preservative, wherein the pH of the emulsion is within the ranges of the instantly claimed pH. The patented claims lack the instantly claimed component of a flexible applicator.

Venkitaraman and Yamanaka teach topical applicators adopted for application of oil-in-water emulsion compositions (abstracts). Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to employ an flexible applicator such as those taught by Venkitaraman or Yamanaka to use the patented compositions of US '236, because the ordinary skill in the art would have had a reasonable expectation of success when using an applicator to apply the patented compositions for their intended topical use.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-5, 20, 24, 26, 28, 30, 34-35, 42-44, 48, 63, 66, 70, 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minoru Kuroda et al JP 58-140013 ('JP 013) (see entire translation) in view of Grollier et al US Patent 4,767,618 (Grollier I), and Venkitaraman et al US Patent 5,871,762.

4. The instant claims are directed to flexible applicators comprising (1) an oil in water emulsion comprising allantoin, beeswax, an anionic surfactant, and an acid to adjust pH of the composition to about 3.0-6.0, wherein the allantoin is being stable in the emulsion for at least 90 days at 40 deg C, (2) a flexible element that adsorbs or absorbs the emulsion for topical administration. Examiner views the novelty of the claimed invention to lie on the emulsion component of the instant claims. Accordingly, since it is known in the art that any topical emulsion needs to be applied to skin, the employment of an applicator is viewed to be conventional. Thus, the rejection essentially is concerned with the patentability of the emulsion and for the reasons set forth below, the claimed invention is *prima facia* obvious over the teachings of the cited art.

5. JP '013 discloses topical oil-in-water emulsions comprising allantoin (see claim 1). The emulsions of JP '013 further contain a higher fatty acid such as stearic acid (a C<sub>18</sub> organic acid) and cetyl alcohol. JP '013 also states that anionic surfactants namely sodium alkyl sulfates such as sodium lauryl sulfate may be employed in such emulsions

if desired (see claims 1, the entire pages 2-3, 5-6, especially examples 1). The pH of the compositions disclosed in JP '013 ranges between 4-7, which overlaps with the instant pH ranges. In fact, JP '013 encourages the use of lower ranges of such pH for improving the stability of allantoin. The compositions taught in JP '013 don't contain beeswax and the instant herbal components such as St. Johns' wort, arnica extract or chamomile extract. Further, JP '013 does not specifically use an applicator for topical administration of the emulsions.

6. Grollier I discloses oil-in-water emulsion compositions that can contain beeswax as a component, which assists oil retention (see col 6, lines 53-56; col 5, line 49). Grollier I also teaches the use of herbal components in such oil-in-water emulsions. The herbal components taught by Grollier I include St. John's wort, chamomile, arnica, or witch hazel (col 3, lines 30-31, 46-56) that can be in the form of powder or extract (see col 2, lines 4-15; col 6, lines 61-64). Grollier I also teaches the use of anionic surfactants such as sodium lauryl sulfate as emulsifying agents (see col 6, lines 5-13), lanolin oil, and cod liver oil as the oil phase (see col 5, line 27-30; col 6, line 40-41), propylene glycol or cetyl alcohol as solvents (col 5, lines 5-12; col 16, lines 30-35), perfume of choice, anti-inflammatory and antiseptic such as allantoin (col 16, line 34-35), a pH modifier, antioxidants such as butyl hydroxyanisole, and preservative agents such as methyl parahydroxybenzoate (methylparaben, see RN 99-76-3), or propyl parahydroxy benzoate (propylparaben, see RN 94-13-3) (see col 6, lines 56-60; col 14, lines 20-23). Grollier I compositions are essentially in the form of emulsions (col 7, lines 9-21).

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7. Vekitaraman's applicator comprises a therapeutic oil-in-water emulsion that can contain an anionic surfactant system and a therapeutic drug (abstract; col 4, lines 14-25 and 43-47). The emulsions used with Venkitaraman's applicator typically has a pH ranging from 2-10 and should be stable for at least 2 days at the temperature of about 120 deg F (about 48 deg C). (see col 2, lines 56-62) which is within the ranges of emulsion systems taught by JP '013. Vekitaraman's applicators also comprise porous or absorbent material, which is impregnated with the oil-in water emulsion and are made of cellulose and polyesters. Accordingly, Venkitaraman meets the limitations of the applicator elements of the instant claims in the form of wipes.

8. It has been held that the selection of known material based on its suitability for its intended use supported a *prima facia* obviousness determination in *Sinclair & Carroll co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the JP '013 emulsions by adding cosmetic components of interest including oil retention agents such as beeswax, and suitable herbal components of choice such as chamomile or St. John's wort, as taught by Grollier I, and finally provide a suitable applicator such as those taught by Venkitaraman's to topically apply such emulsions.

9. The ordinary skill in the art would have had a reasonable expectation of success in combining the above recited components, since it has been reasoned that reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle. *Sinclair & Carroll co.*, 325 U.S. at 335, 65 USPQ at 301. Thus, since all elements of the instant

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claims are taught in the cited references to be employed in oil-in-water emulsion systems combining them for their own intended use and further applying it with an applicator would have been *prima facia* obvious.

10. Claims 1-11, 20-21, 24, 26, 28, 30, 32, 34-35, 38-39, 42-44, 48, 56, 59, 63, 66, 70, 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minoru Kuroda et al JP 58-140013 ('JP 013) (see entire translation) in view of Grollier et al US Patent 4,767,618 (Grollier I), and Venkitaraman et al US Patent 5,871,762, as applied to claims 1-5, 20, 24, 26, 28, 30, 34-35, 42-44, 48, 63, 66, 70, 73 and further in view of Grollier US Patent 4,880,621 (Grollier II), Chodosh US Patent 5,661,170, Briggs et al US Patent 5,871,754, and Yamanaka et al US Patent 5,176,916, as applied to claim 6-11, 21, 32, 38-39, 56, 59.

11. The teaching of JP '013, Grollier I and Venkitaraman are discussed above. Their combined teachings fail to explicitly teach the use of butylated hydroxytoluene as an antioxidant, citric acid and hydrochloride acid as pH modifiers, EDTA as the chelator, and bandages as an applicator component.

12. Grollier II is essentially the same teachings as Grollier I, except that it also sets forth that antioxidants such as butyl hydroxytoluene and butyl hydroxyanisole are art recognized equivalents (see col 8, lines 42-44; col 9, lines 43-45). Grollier II, however, fails to employ an applicator for administration of his emulsions topically.

13. Chodosh is merely used to show that citric acid is conventionally employed as a pH modifier in allantoin containing emulsions and that it along with ascorbic acid and malic acid, and strong acids such as hydrochloric acid are conventional acidifying

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agents. Further, Chodosh provides for formulations that may be administered with topical wipes (see col 5, lines 5-55; col 7, lines 1-7 and line 36). Briggs also teaches allantoin oil-in-water emulsions, but it is used to show that chelating agents such as EDTA are among conventional adjuvants used in oil-in-water emulsion systems (see col 10, lines 45-col 11, lines 10).

14. Venkitaraman and Yamanaka teach various flexible applicators for topical administration of oil-in-water emulsions (abstract). Venkitaraman's applicator are described above. Similarly, Yamanaka teach polymeric applicators in the form of bandages that are readily used for administration of topical formulations such as oil-in-water emulsions (see abstract, col 3, lines 64-col 5, line 10; col 13, lines 8-26).

Venkitaraman's and Yamanaka's applicators lack an oil-in-water emulsion containing allantoin.

15. The teachings of Kuroda, Grollier, Chodosh, Venkitaraman, Yamanaka, and Briggs are considered to be in the same field of endeavor, because they all provide for topical administration of oil-in-water emulsion systems.

16. It has been held that the selection of known material based on its suitability for its intended use supported a *prima facia* obviousness determination in *Sinclair & Carroll co. V. Interchemcial Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the JP '013 emulsions by adding cosmetic components of interest including oil retention agents such as beeswax, emollients such as cetyl alcohol, herbal components of choice such as chamomile or St. John's wort, and other topical adjuncts such as preservatives

as taught and pH modifiers including citric acid, antioxidants such as butylhydroxytoluene, and a chelating agent such as EDTA, as taught by Grollier I and II, and further exemplified by Chodosh and Briggs, and finally provide a suitable applicator such as those taught by Venkitaraman's or Yamanaka, to topically apply such emulsions.

17. The ordinary skill in the art would have had a reasonable expectation of success in combining the above recited components, since it has been reasoned that reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle. *Sinclair & Carroll co.*, 325 U.S. at 335, 65 USPQ at 301. Thus, since all elements of the instant claims are taught in the cited references to be employed in oil-in-water emulsion systems combining them for their own intended use and further applying it with an applicator would have been *prima facia* obvious.

***Allowable Subject Matter***

18. Claims 49-55, 60-62, 67-69, 74-76, are free of art, because the recited concentration of each component of within the emulsion is not taught in the prior art and thus there is no expectation of success in the art to render such combination obvious.

***Conclusion***

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.



Shahnaz Sharareh  
Patent Examiner, Art Unit 1617

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June 2, 2003